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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/615,736	07/13/2000	David Frederick Horrobin	P65773US0	4938

7590 05/24/2004

Jacobson Price Holman & Stern
Professional Limited Liability Company
400 Seventh Street NW
Washington, DC 20004

EXAMINER	
PESELEV, ELLI	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 05/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/615,736	HORROBIN ET AL.	
	Examiner	Art Unit	
	Elli Peselev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *April 9, 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-19,22-26,37-39 and 46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-19, 22-26, 37-39 and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The disclosure is objected to because of the following informalities: the section titled "Brief Description of the Drawing" is missing.

Appropriate correction is required.

Claims 16-26, 37-39 and 46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The term "derivative" as applied to EPA is not disclosed or suggested by the specification as originally filed. The disclosure on page 8 of the specification of a single derivative i.e. does not provide support for all possible derivatives of EPA.

Claims 16-19, 22-26, 37-39 and 46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for ethylester of EPA, does not reasonably provide enablement for all possible derivatives of EPA. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The term "derivative" encompass a large number of possible derivatives of EPA. The specification fails to provide any teaching or guidance of how to chose and make derivatives of EPA which will be useful in the claimed compositions and method with the exception of ethylester. It would take an undue amount of experimentation to determine what additional derivatives will be useful in the claimed invention.

Claim 46 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Improper markush group has been used to list the diseases in claim 46 i.e. the term "or" is missing between the last two species of the Markush group. The terminology "phychiatric disorder" and "neurological disorder" encompass the other species of the Markush group.

It is not clear what is encompassed by the terminology "other schizophreni form disorder".

Claim 46 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 46 is directed to the treatment of a psychiatric disorder, schizophrenia, a schizotypal disorder, other schizophrenic form disorder, bipolar disorder, a sleep disorder, a social phobia, a neurological disorder, a neurodegenerative disorder, Alzheimer's disease, dementia, Parkinson's disease, multiple sclerosis and Huntington's disease. The specification fails to provide any evidence that the claimed method is effective in treating any of the disorders encompassed by claim 46. Since the treatment of the disorders listed in claim 46 is highly unpredictabe, there is a good reason to doubt that the claimed method is effective in treating any of the disorders listed in claim 46.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16-19, 22-26, 38-39 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heijer et al in combination with Horrobin and Hglund et al for the reasons set forth in the Office Action of May 12, 2003.

Applicant's arguments filed April 9, 2004 have been considered but have not been found persuasive.

Horrobin discloses EPA to be an essential fatty acid. Further, the cited prior art discloses vitamin B6, vitamin B12 and folic acid to be essential nutrients. A person having ordinary skill in the art at the time the instant invention was made would have been motivated to combine well known nutrients into a single composition and to vary

the amounts of said nutrients in order to provide a more complete nutritional supplement.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 9.00-5.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elli Peselev

ELLI PESELEV
PRIMARY EXAMINER
GROUP 1200